OPTN/UNOS TRANSPLANT ADMINISTRATORS COMMITTEE
Report to the Board of Directors
November 8-9, 2010
St. Louis, MO

SUMMARY

I. Action Items for Board Consideration:

- None

II. Other Significant Items:

- The Committee continues to support various committee Work Groups by providing the transplant administrator perspective on proposals prior to being released for public comment. (Item 1, Page 3)

- The Committee will continue developing DonorNet® educational tools for the transplant community. (Item 1, Page 5)

- The bi-annual payer meeting was held in Chicago, IL on July 15, 2010. (Item 4, Page7)

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REPORT OF THE
OPTN/UNOS TRANSPLANT ADMINISTRATORS COMMITTEE
TO THE BOARD OF DIRECTORS
November 8-9, 2010
St. Louis, MO

Gene E. Ridolfi, BA, RN, Chair
Timothy J. Stevens, RN, BSN, CCTC, Vice Chair

The Committee meets monthly by conference call/Live Meeting except in April, when the Transplant Management Forum occurs, and July and October when the Committee meets in person.

1. Committee Goals- The Committee continues to devote considerable time to working on the goals that were presented to the Executive Committee. Those goals are:

   - To provide input regarding all proposals with potential to impact transplant program operations, and particularly with regard to: Member and patient communications regarding a new kidney allocation system and the OPTN kidney paired donation program (KPD); and proposed revisions to living donor data submission policies and forms. The Committee had some suggestions regarding the KPD pilot program including the development of standardized contractual language for centers to utilize; and that a CMS representative become involved with the KPD pilot program to weigh in on cost reporting and other financial issues that may arise related to KPD. This same request was also raised on the KPD Finance Subcommittee conference call on April 14, 2010. The Committee was made aware that HRSA and UNOS are discussing payment for all aspects of KPD with CMS to include travel, donor management, follow- up care, shipping, etc. The Committee will continue to have crossover Work Group representatives on the KPD Work Groups to provide the full committee with updates during the Transplant Administrators Committee (TAC) monthly conference calls and in-person meetings.

     The Committee also provided feedback to the Living Donor Committee (LDC) regarding the LDC Follow–up Practices Survey and pre-proposals.

     On December 8, 2009, the Living Donor Committee requested that the TAC help identify initiatives that would provide financial coverage for living donor follow-up for submission of follow-up data. The Living Donor Committee requested that the TAC identify best practices, and/or to identify existing impediments to obtaining living donor follow-up.

     The TAC's response to the LDC's request described below was submitted to the LDC for consideration on February 22, 2010:

     A small workgroup was formed to review the Living Donor Committee's request and to formulate the potential actions to address these key issues. The Committee suggests the following:

     Identify initiatives that would provide financial coverage for living donor follow-up
     - Solicit grants for funding of future donor complications
     - Enlist the assistance of HRSA to engage CMS in discussions regarding the addition of Living Donor follow-up on the Medicare Cost Report

- Evaluate only Living Donors with their own personal healthcare coverage for any long term needs which may occur
- Evaluate only Living Donors with proof of US citizenship
- Negotiate with payers for improved coverage of living donation and the required 2 year follow-up costs

Identify what is considered best practice and/or to identify existing impediments to obtaining living donor follow-up

- Offer Saturday follow-up appointments to Living Donors. This would be for those donors who are employed as this currently tends to be a barrier to follow-up
- Provide focused education during the evaluation phase to the living donors on the requirement of 2 years of follow-up with the transplant center
- Providing the donor with just a statement or having the donor sign a form in the evaluation phase may not be the most effective means of communicating the importance of living donor follow up to the donor
- Explore state and/or federal income tax incentives (deductions) for living donors that comply with the 2 year follow-up requirement. This might help with the donor's reluctance to maintain the follow-up
- Explore ways to obtain Medicare economic support to transplant centers for living donation (Currently, this is an unfunded mandate for the transplant centers.)
- Require transplant center social workers to do reminder calls to living donors when the next follow-up appointment is imminent. (Increased time constraints on the Nurse Coordinators do not allow for focused reminders to donors)

Any of the above suggestions for improved financial coverage and overcoming the existing barriers to obtaining living donor follow-up for two years will not be easy tasks.

The Committee reviewed the LD Follow–up Practices Survey, which was developed to learn more about how individual transplant programs conduct follow-up with their living donors after donation surgery. The goal of the survey was to learn what transplant programs see as their strengths and weaknesses in monitoring living donors over time. The Committee approved the survey and agreed to co-sponsor and promote completion of the survey within the transplant community.

Amy Waterman, MD, LDC Vice Chair presented the Living Donor Follow- up Practices Survey results and reported the LDCs updates to the TAC. The Committee requested clarification on the driving factor for increasing compliance for LD follow-up. Dr. Waterman responded that increased compliance with LD follow-up will improve patient safety and trust in the living donation system. The Committee also inquired as to whether or not CMS has been approached about costs and Medicare paying for LD follow-up. It was questioned why LD follow-up costs could not be included in the Standard Acquisition Charge (SAC). The TAC HRSA representative stated that CMS is not enthusiastic about paying for LD follow-up but the conversation will continue to occur. The Committee stated that the main issue with LD follow-up is that transplant centers have depleted their resources to complete the reports. One Committee member stated that the key to LD follow-up is hiring a dedicated LD advocate/coordinator, and the center pay for all LD laboratory work no matter where the laboratory work was completed. Another Committee member suggested changing the way the laboratory results are entered into LD follow-up form. For example, if the "lost due to follow-up" field is marked, then the center should not be able to enter the laboratory results into the form.

The LDC requested feedback from the Committee on the concept of using OPOs to facilitate the packaging and shipment of living donor organs, anticipated obstacles, and how OPOs should be compensated for this possible new role. **(Exhibit A)** A small Work Group was formed to address the request, and the TAC feedback was submitted to the LDC on August 24, 2010. **(Exhibit B)**

The Committee received an overview of the Operations and Safety Committee's Vessel Storage Policy Proposal and discussed ways to improve compliance. The TAC agreed that centers need to work closely with the operating room (OR) because the transplant center is responsible for compliance even though the vessels are stored in the OR. Some suggestions on improving compliance were that transplant administrators need to have standing meetings with the OR staff to ensure reports are being completed and work to develop effective processes for completing these reports; have a person who audits OR records to make sure the records are in compliance; and set a specific day and time for the primary surgeon to meet with staff and complete paperwork. Another concern the TAC raised was the impact this proposal will have on transplant center operations and workload. It was also suggested that best practices be developed to ensure compliance.

The Committee received a presentation from the Patient Affairs Committee Liaison regarding patient notification bylaws and the patient notification letter. The TAC requested clarification regarding if the transplant center needs to keep a hard copy of the patient notification letter in the patient's chart. The Committee also requested that the reading level of the patient notification letter be lowered. It was later clarified that centers do not need to retain a hard copy of the patient notification letter in the patient's chart but there needs to be documentation in the chart that the letter was provided.

The Pancreas for Technical Reasons Work Group minutes were reported to the Committee. No other meetings with this Work Group have occurred since April 29, 2010. It was reported that UNOS continues to track if the pancreas is being transplanted as a multi-visceral transplant with the liver or intestine. The Committee will continue to have a crossover Work Group representative to provide the full committee with the Work Group's updates on the TAC monthly conference calls.

The TAC has representatives on various committee Work Groups. These Work Groups include: KPD, KPD Financial Subcommittee, Policy Rewrite, Pancreas for Technical Reasons, Living Donor, Patient Safety Review, When Donor Data Changes, and Operations and Safety Vessel Policy and Vessel Packaging and Labeling. At this time, these TAC representatives participate in Live Meetings with these Work Groups to provide the transplant administrator perspective on proposals that evolve from the Work Group's sponsoring committees. These representatives are also responsible for reporting any Work Group updates and activities on the TAC monthly Live Meetings.

- <u>To develop educational strategies for members regarding more effective use of DonorNet®.</u>
  The TAC DonorNet® Work Group partnered with the OPO Committee to develop a list of standardized abbreviations that would be acceptable to use in DonorNet®. This Work Group was formed due to the miscommunication between OPOs and transplant centers when the OPOs enter information into DonorNet® and use abbreviations that may not be standardized. The use of non-standardized abbreviations could pose a significant patient safety risk if the transplant center misinterprets the information being conveyed. The TAC DonorNet® Work Group evaluated the use of abbreviations throughout the country and arrived at a list that contained 490 abbreviations. It was decided that this list was too extensive and needed to have a limited number of

abbreviations so individuals would actually utilize the list when entering information into DonorNet®. The OPO Work Group agreed that the list would be more user friendly if there were specific categories formed for those acceptable abbreviations such as lab values, national units of measure, periodic table of chemical elements, etc., and only a brief list of acceptable abbreviations that did not fit within the stated acceptable categories (i.e., r/o instead of rule out). The OPO Work Group submitted its recommendations to the TAC DonorNet® Work Group for review. The TAC approved the OPO Committee's recommendations and has requested that the Operations and Safety and the Transplant Coordinators (TCC) Committees also review and provide feedback on the document. After all feedback has been received, the goal will be to disseminate the document to the transplant community through listservs, AOPO portal and with any other DonorNet® educational materials that are distributed to the transplant community. The Work Group will also consider developing other DonorNet® educational resources.

- To partner with appropriate committees and develop strategies for improved Wait List Management within transplant centers. The TCC created and administered a survey, which was used to study real-world practices, timing, and communication related to listing and managing candidates at inactive status on the waitlist. It was the intent of the TCC to study the results and use them to help develop inactive waitlist management best practices. The TAC had three members that worked with the TCC on reviewing the results of the waitlist survey. The TCC presented the findings at the 2010 Transplant Management Forum in a breakout session.

- Long Term Goal: To work with staff to develop potential strategies for improving the quality of data submission. The Committee will provide ideas regarding improving program specific reports by discussing concerns with the program specific reports and ideas to address those concerns.

2. 2010 Transplant Management Forum. The 2010 Transplant Management Forum was held April 21-23 in Orlando, Florida. A total of 418 participants attended the meeting. The Committee accepted a total of 45 abstracts. There were 40 exhibitors, 9 sponsors and 6 abstract award sponsors supporting the meeting. The agenda included eight plenary sessions and four breakout session tracks. The 2011 Transplant Management Forum will be in Denver, Colorado on April 18-20. The Committee has received several suggestions for 2011 sessions, and the agenda planning has begun.

3. Staffing Survey. The Committee continues to evaluate how the staffing survey might be helpful and useful for the MPSC as it evaluates new program applications or considers the performance of centers having outcome problems. The 2009 Staffing Survey was released on the Transplant Administrators section of the UNOS Secure Enterprise Web Site in late February. Comparison statistics for transplant program staffing with the 2010 data are available to any member who has already submitted a survey. As in prior years, only programs that complete surveys for their organ specific programs will have access to the summary and comparison data. The goal for the 2010 Staffing Survey is to have 75% of all transplant programs complete the surveys in each organ specific grouping. This goal will be reconsidered at the October in person committee meeting. As of mid-September, response rates range from 19% for heart to 25% for lung programs. This is well below the participation levels in previous years and represents a declining trend from the peak of the 2006 survey year (31% to 51% depending on program). Several reminders have been sent to the community by UNOS e-Newsletter and listserv messages. Each notice elicited some submission activity and inquiries, but the overall response remains low. The TAC Staffing Work Group is in the midst of reviewing the survey tool and report with an eye towards making it more useful and easier to complete. The Work Group has reached out to the administrator community to solicit ideas and find out what would encourage them to submit a survey. The Work Group hopes to release a revamped survey in 2011.

4. Request for Information Payer Work Group. The Committee continues to explore how the Request For Information (RFI) payer group could assist UNOS in understanding the perspectives and concerns of payers while balancing the needs of transplant centers for adequate reimbursement. The Committee held its bi-annual payers meeting, and the Payer Work Group met with selected payers in Chicago to discuss updates/changes that should be made to the current RFI. The American Society for Bone Marrow Transplant (ASBMT); James Long, MD, Medical Director, Advanced Heart Failure Program at INTEGRIS Baptist Medical Center and John Friedewald, MD from Northwestern Memorial Hospital were all invited speakers for this meeting. The ASBMT presented their RFI and received recommendations from the payers, which they will take back to their board. Dr. Long's presentation educated the payers on the past and future of Ventricular Assist Devices (VADs) and Dr. Friedewald provided an update on the KPD pilot program. The payers provided feedback to the TAC regarding updates to the UNOS Standardized RFI. The two updates the payers approved included the removal of question F-12, which has to do with readmission rates and revisions to the VADs table on the heart RFI to include only the past three years of data and centers only need to report that a device was used for bridge to transplant. Annual updates along with the payer approved revisions to the RFI will be submitted to UNOS in October. Future Work Group initiatives include developing a FAQ document and RFI field definitions. The RFI will be released late January 2011.

5. Public Comment Responses. The Committee discussed and made recommendations for the following proposals released for public comment:

   1. **Proposed Ohio Alternative Local Unit (ALU) Liver and Intestinal Organ Transplantation Committee (Liver and Intestinal Organ Transplantation Committee)**

      Committee Response: No comment.

   2. **Proposed OneLegacy Variance for Segmental Liver Transplantation (Liver and Intestinal Organ Transplantation Committee)**

      Committee Response: No comment.

   3. **Proposed Region 2 Variance for Segmental Liver Transplantation (Liver and Intestinal Organ Transplantation Committee)**

      Committee Response: No comment.

   4. **Proposal to Develop an Efficient, Uniform National Pancreas Allocation System: Affected Policies: Policy 3.8 (Pancreas Allocation Policy), Policy 3.5 (Kidney Allocation Policy), Policy 3.2 (Waiting List), Policy 3.3 (Acceptance Criteria), Policy 3.4 (Organ Procurement, Distribution And Alternative Systems For Organ Distribution Or Allocation), and Policy 3.9 (Allocation Systems for Organs not Specifically Addressed) (Pancreas Transplantation Committee)**

      Committee Response: The Committee reviewed and unanimously voted to support this proposal as written (Support 11, Oppose 0, Abstain 0).

   5. **Proposal to Modify OPO and Transplant Center Requirements for Screening, Communicating and Reporting All Potential or Confirmed Donor-Related Disease and Malignancy Transmission Events: Affected/Proposed Policies: Policies 2.0 (Minimum Procurement Standards for An Organ Procurement Organization), 4.0 (Acquired Immune Deficiency Syndrome (AIDS), Human Pituitary Derived Growth Hormone (HPDGH), and**

Reporting of Potential Diseases or Medical Conditions, Including Malignancies, of Donor Origin), and 5.5 (Documentation Accompanying the Organ or Vessel) (Ad Hoc Disease Transmission Advisory Committee)

Committee Response: The Committee did not vote on the proposal, but has the following recommendations.

- *Under 2.1 Host OPO under the added phrase "complying with accepted practice and OPTN policy throughout the donation process," and organ allocation, the Committee recommends deleting the wording " accepted practice and." While it is appropriate to say OPOs and transplant centers need to comply with OPTN policy, it is beyond UNOS's purview to make overly broad and non-specific statements like the phrase that needs to be deleted. This wording would expose OPOs and transplant centers to liability concerns.*

- *Under 2.2.2.1 Obtaining the Donor's medical/behavior history, the Committee recommends that in the second paragraph the words "or prior disease," be deleted. The policy is not specific and should specify if there are specific prion diseases that should be named. This is overly broad and non-specific, inappropriate for this OPTN policy, and once again if made policy it would expose OPOs and transplant centers to liability.*

- *Under 2.2.3.1, greater specificity is needed in a policy format. The Committee recommends the following wording be added to the second paragraph:"If a non-hemodiluted specimen is not available for testing, a hemodiluted specimen should be used for testing purposes." Then the paragraph can continue as written.*

- *Under 2.2.3.3, the Committee recommends removing the word "unequivocally." This wording goes beyond the policy making scope of UNOS and would expose OPOs and transplant centers to liability.*

- *Under 2.2.3.4, the Committee recommends removing the words "Host OPO" as the OPO has no knowledge of the recipient or his/her status and therefore should not be responsible for making a clinical determination regarding recipients.*

- *Under 2.2.5 Follow-up on Donor Testing, the Committee recommends the paragraph should read as follows: "The Host OPO must establish a procedure that defines it process for obtaining post recovery donor testing results ~~from the hospital where donor recovery took place."~~ Testing can take place in locations other than just the donor hospital. The wording proposed will more accurately address what DTAC is trying to accomplish.*

There was requested clarification regarding the use of the specific language "potential disease transmission" and "confirmed disease transmission." Dr. Michael Ison, DTAC Ex. Officio, clarified that a potential disease transmission notification may not be appropriate and although not a requirement, it may be better to only notify patients in cases where disease transmission is confirmed. Patient notification is left to the transplant center's discretion.

There was also discussion regarding the patient safety contact process (e.g. between the transplant center, OPO, OPTN, and CDC). A member stated that there is not a central contact for this process and that needs to be considered. Dr. Ison informed the Committee that the OPTN cannot dictate the actions of the CDC. It is intended for the OPO to be the central contact for information that is shared with the individual transplant center and the OPTN.

6. **Proposal to Update HLA Equivalences Tables Affected/Proposed Policy: UNOS Policy 3 Appendix A (Histocompatibility Committee)**

   Committee Response: The Committee reviewed and unanimously voted to support this proposal as written (Support 11, Oppose 0, Abstain 0).

7. **Proposal to Require that Deceased Donor HLA Typing be Performed by DNA Methods and Identify Additional Antigens for Kidney, Kidney-pancreas, Pancreas, and Pancreas Islet Offers Affected/Proposed Policy: UNOS Bylaws Appendix B Attachment IIA - Standards for Histocompatibility Testing D HLA Typing D1.000 Essential Information for Kidney Offers 3.8.2.2 Essential Information for Pancreas Offers (Histocompatibility Committee)**

   Committee Response: The Committee reviewed and unanimously voted to support this proposal as written (Support 11, Oppose 0, Abstain 0).

8. **Proposal for the Placement of Non-Directed Living Donor Kidneys: Affected Policy: 12.5.6 (Recipient Selection for Organs from Nondirected Living Donor Organs) (Living Donor Committee)**

   Committee Response: The Committee reviewed and voted to support this proposal but would like the Living Donor Committee to clarify why the OPO needs to run the match run when some transplant centers can run their own internal match run. (Support 11, Oppose 0, Abstain 0).

9. **Proposal to Require Reporting of Non-utilized and Redirected Living Donor Organs - New Proposed Policy: Submission of Non-utilized Living Donor Organs (Policy 12.8.5) and Submission of Redirected Living Donor Organs (Policy 12.8.6) (Living Donor Committee)**

   Committee Response: The Committee reviewed and unanimously voted to support this proposal as written (Support 11, Oppose 0, Abstain 0).

10. **Proposal to Require a Use of a Standardized, Internal Label that is Distributed by the OPTN and that Transplant Centers Notify the Recovering OPO when they Repackage an Organ Affected/Proposed Policy: Policy 5.0 – Standardized Packaging, Labeling and Transporting of Organs, Vessels and Tissue Typing Materials (Organ Procurement Organization (OPO) Committee)**

    Committee Response: The Committee reviewed and unanimously voted to support this proposal as written (Support 11, Oppose 0, Abstain 0). A Committee member suggested that in the future the OPO Committee consider that labels have bar codes for tracking purposes. Another member questioned the possibility of mandating that only OPOs handle repackaging organs. It was noted that this would be a difficult mandate.

OPTN/UNOS Transplant Administrators Committee
July 15-16, 2010
Chicago, IL

Committee Members in Attendance	
Gene E. Ridolfi BA, RN	Chair
Timothy Stevens RN, BSN, CCTC	Vice Chair
Sharon Mathews MS, RN, CPTC	Region 1 Representative
Sylvia Odom RN, MSN, NHS, CCTC	Region 3 Representative
Katherine Stark MHSA	Region 4 Representative
Amy Peele	Region 5 Representative
Pamela Hester RN, BSN, CCTC	Region 6 Representative
David Hester	Region 7 Representative
Nancy Long RN, CCTC	Region 8 Representative
Nancy Metzler	Region 9 Representative
Katherine Evers RN, BSN, MBA	Region 10 Representative
Robert Teaster RN, MBA, CPTC	Region 11 Representative
Leroy Walker	At Large
Vikram Acharya BS, MPH	At Large
Robert Walsh	Division of Transplantation, Ex Officio, non-voting
Holly Berilla MSW	Division of Transplantation, Ex Officio, non-voting

Committee Members Unable to Attend	
Kim Barnett RN, BSN, CCTC	Region 2 Representative
James Cutler CPTC	At Large
Jacqueline Colleran	At Large
Mesmin Germain, MBA, MPH	Division of Transplantation, Ex Officio, non-voting

Staff in Attendance	
Angel Carroll MSW	Liaison
Cherri Carwile	Assistant Liaison
Jude Maghirang MS	UNOS Staff
Lin McGaw RN, MEd	Director of Professional Services
John Lombardi	UNOS Staff
Melissa Fava	SRTR Liaison
Manny Carwile	UNOS IT Staff
Erma Edmiston	UNOS Travel Staff
Kerrie Cobb	UNOS Staff

OPTN/UNOS Transplant Administrators Committee
Payer Meeting Attendance
July 15, 2010
Chicago, IL

Janie Morrison FACHE	TAC Payer Work Group, Chair
Gary Sigle RN, MBA, BSN	TAC Payer Work Group Member
Gene E. Ridolfi BA, RN	TAC Payer Work Group Member
Timothy Stevens RN, BSN, CCTC	TAC Payer Work Group Member
Sharon Mathews MS, RN, CPTC	TAC Payer Work Group Member
Sylvia Odom RN MSN, NHS, CCTC	TAC Payer Work Group Member
Angel Carroll MSW	Liaison
Cherri Carwile	Assistant Liaison
Jude Maghirang MS	UNOS Staff
Lin McGaw RN, MEd	Director of Professional Services
John Lombardi	UNOS Staff
Robert Walsh	Division of Transplantation, Ex Officio, non-voting
Holly Berilla MSW	Division of Transplantation, Ex Officio, non-voting
Michael Boo	National Marrow Donor Program
Aaron Schnell	National Marrow Donor Program
Stephanie Farnia	National Marrow Donor Program
James Gajewski MD	Oregon Health & Science University
Peggy Appel	Northwest Marrow Transplant Program
Adriana Marianni	Cigna LifeSource Transplant Network
Patricia Martin	Anthem
Anthony Bonagura MD	Aetna
Stephen Crawford MD	Cigna LifeSource Transplant Network
Douglas Rizzo MD	Center for International Blood and Marrow Transplant Research
Jon Friedman MD	OptumHealth
Frank Irwin MD	OptumHealth
Celia Clarke	Kaiser Permanente
Wendy Marinkovich	Blue Cross/Blue Shield
Rose Baez	Blue Cross/Blue Shield
Jennifer Nowak	Blue Cross/Blue Shield
James Long MD	INTEGRIS Baptist Medical Center
Karl Nelson	INTEGRIS Baptist Medical Center
John Friedewald MD	Northwestern Memorial Hospital
Gary Miles	LifeTrac Network
Susan McKevitt	LifeTrac Network
Cathy Kraemer	National Transplant Contracting Humana, Inc.
Robert Krawisz	ASBMT
Patrick Stiff MD	Loyloa University Medical Center
Julie Walz	Multiplan
Cindy Mathews	INTERLINK